UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

In Re: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION

MDL NO. 2740

SECTION "H" (5)

THIS DOCUMENT RELATES TO:
ALL CASES

DEFENDANTS' MOTION TO RECONSIDER AND VACATE CMO 36 AND TO STRIKE GENERAL EXPERTS' IMPROPER TESTIMONY

Defendants sanofi-aventis U.S., LLC and Sanofi US Services, Inc. ("Sanofi") respectfully move this Court to reconsider its Order Granting the PSC's Motion to Preserve Expert Testimony and vacate CMO 36. Sanofi also requests that the Court strike Dr. Feigal and Dr. Madigan's preservation testimony that violates the limitations imposed by CMO 36.

At the PSC's request, this Court entered CMO 36 permitting "expert preservation depositions" of "general" experts for potential use at trial in transferred cases. The PSC, however, has flouted CMO 36 in the two preservation depositions taken to date. Dr. Ellen Feigal and Dr. David Madigan have offered opinions that have (1) never been properly disclosed; (2) been previously ruled inadmissible by this Court; and (3) referenced evidence this Court excluded under Rule 407. It is clear now that the PSC hopes to repackage inadmissible testimony as admissible testimony in the transferor courts under the guise of CMO 36. Such a strategy has eviscerated the perceived efficiencies of CMO 36, and it raises substantial prejudice to Sanofi in the process. As a result, Sanofi requests that the Court vacate CMO 36 and strike Dr. Feigal and Dr. Madigan's preservation testimony that violates the limitations imposed by CMO 36.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 9, 2023, I electronically filed the foregoing with the Clerk of the Court using the ECF system, which sent notification of such filing to all counsel of record.

/s/ *Douglas J. Moore*

MEMORANDUM IN SUPPORT

Filed Under Seal

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

In Re: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION

MDL NO. 2740

SECTION "H" (5)

THIS DOCUMENT RELATES TO:
ALL CASES

DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO RECONSIDER AND VACATE CMO 36 AND TO STRIKE GENERAL EXPERTS' IMPROPER TESTIMONY

At the PSC's request, this Court entered CMO 36 permitting "expert preservation depositions" of "general" experts for potential use at trial in transferred cases. Because "the concept of *de bene esse* depositions . . . within the current Federal Rules of Civil Procedure is questionable," CMO 36 confers certain protections. *See La. Real Est. Appraisers Bd. v. U.S. Fed. Trade Comm'n*, 2020 WL 1817297, at *3 (M.D. La. Apr. 9, 2020) (citation omitted)). Specifically, CMO 36 requires (1) the opinions be properly disclosed, and discovered; (2) the opinions be admissible under Rule 702 as determined by this Court; and (3) the testimony be consistent with the Court's prior evidentiary rulings.[1]

The PSC has flouted CMO 36 in the two preservation depositions taken to date. Dr. Ellen Feigal and Dr. David Madigan have offered opinions that have (1) never been properly disclosed; (2) been previously ruled inadmissible by this Court; and (3) referenced evidence this Court excluded under Rule 407. It is clear now that the PSC hopes to repackage inadmissible testimony as admissible testimony in the transferor courts under the guise of CMO 36. Such a strategy has eviscerated the perceived efficiencies of CMO 36, and it raises substantial prejudice to Sanofi in the process. As a result, Sanofi requests that the Court reconsider its Order Granting the PSC's

[1] Rec. Doc. 14925 (CMO 36).

Motion to Preserve Expert Testimony and vacate CMO 36.[2] Sanofi also requests that the Court strike Dr. Feigal and Dr. Madigan's preservation testimony that violates the limitations imposed by CMO 36.

BACKGROUND

In seeking to preserve expert testimony, the PSC told the Court one thing, then proceeded to do the opposite. Repeatedly. The PSC explained to the Court that "[p]reservation depositions, especially after *Daubert* determinations[,] will define the proper scope of that testimony."[3] The PSC further stated that its request would "preserve and eliminate duplicative expert discovery by allowing this [C]ourt to address once again and once and for all the issues of the [Rule] 702 challenges to our general experts."[4] And consistent with those representations, the Court entered CMO 36, which provided that preservation depositions would be "subject to the Court's prior rulings as they relate to these witnesses," including "the Rule 702 rulings entered by this Court."[5] The Order also required that an expert's opinions be contained in a previously disclosed expert report, or a supplemental report that would be subject to additional discovery.[6]

But once CMO 36 was entered, the PSC ignored it. During both the depositions of Dr. Feigal and Dr. Madigan, the PSC elicited new or previously excluded opinions from its experts in a calculated effort to introduce these inadmissible opinions in the transferor courts. One mistake might be explained. The following are not.

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2 Rec. Docs. 14925, 13981 (Order Granting PSC's Mot. to Preserve Expert Test.).

3 Rec. Doc. 12729-1 at 2 (PSC's Mot. to Preserve Expert Test.).

4 **Ex. A**, Hr'g Tr. 3:25–4:4 (Mar. 8, 2022); *see also id.* at 8:11–16.

5 Rec. Doc. 14925 at 2, 6.

6 *Id.* at 4–5.

Dr. Feigal

Dr. Feigal's Causation Opinions on Other Chemotherapies: Dr. Feigal testified that based on her analysis there was insufficient evidence to conclude that non-Taxotere chemotherapies, such as Adriamycin and Cytoxan, can cause PCIA.[7] These opinions are not in Dr. Feigal's expert report, which she conceded:

> Q. And nowhere in your expert report do you render those opinions, do you? Nowhere in your expert report do you say, "I conducted the analysis and I have determined that Adriamycin cannot cause PCIA"?
>
> A. I do not have that exact sentence, that's correct.
>
> Q. And I think you were asked the same sort of questions about cyclophosphamide and Taxol as well by Mr. Miceli; correct?
>
> A. Correct.
>
> Q. And you didn't have any opinions about whether or not those agents can cause or are capable of causing PCIA in your expert report, did you?
>
> A. In the expert report, I don't have that exact sentence, that's correct.[8]

Although Dr. Feigal was more than willing to render these opinions for the first time during her preservation deposition, she repeatedly testified in her prior discovery depositions that she has never conducted an analysis that would enable her make to such determinations and expressly disclaimed holding those opinions at that time:

> Q. . . . In reaching your conclusions about whether Taxotere is capable of causing PCIA, did you determine whether Adriamycin is also capable of causing PCIA?
>
> A. I did not do a Bradford-Hill analysis on Adriamycin.
>
> Q. In reaching your conclusion on whether Taxotere is capable

[7] **Ex. B**, Feigal Dep. 44:1–46:2 (Jan. 26, 2023).

[8] **Ex. C**, Feigal Dep. 262:8–24 (Jan. 27, 2023).

> of causing PCIA, did you determine whether cyclophosphamide is capable of causing PCIA?
>
> A. I did not do a Bradford-Hill analysis on cyclophosphamide.[9]
>
> ***
>
> Q. Would it be an appropriate takeaway from reading your expert report to say that Adriamycin, cyclophosphamide, aromatase inhibitors or paclitaxel do not cause pCIA?
>
> MR. MICELI: Object to the form.
>
> A. What you can say from my report is about the causation of docetaxel/Taxotere. I'm not opining on other products that aren't the topic for the litigation.
>
> Q. Okay. So I think that answered my question. So –
>
> A. Okay.
>
> Q. -- you could not take away from reading your report that those other medications do not cause pCIA, correct?
>
> A. I'm silent on that.
>
> MR. MICELI: Object to the form.
>
> A. Yeah. I mean, I'm talking about risk and causal association of docetaxel/Taxotere so, you know, I can't comment any further than that.[10]

Dr. Feigal's References to Excluded Evidence: Dr. Feigal also made repeated references during cross-examination to Sanofi label changes that were previously excluded by this Court under Rule 407.[11]

> Q. And so what I want to do is just ask you, given that we have these two tables, both coming from Sanofi, one definitely submitted to a regulator, one -- maybe it was or maybe there's a

[9] **Ex. D**, Feigal Dep. 83:11–24 (Apr. 10, 2020).

[10] **Ex. E**, Feigal Dep. 141:4–25 (Sept. 1, 2020).

[11] Rec. Docs. 8201 at 6 (Order and Reasons in *Earnest*); 13260 at 8 (Order and Reasons in *Kahn*).

similar version submitted to a regulator – that have different follow-up periods. How can we figure out which one's correct?

MR. MICELI: Objection to form.

A. Well, you're talking about apples and oranges. The follow-up that Sanofi did submit to the European agency in response to their question about persistent or long-lasting permanent alopecia came back with 29 and 16. That's Sanofi. I'm not manipulating the numbers. That is what they told the agency.

BY MR. MOORE:

Q. Yes.

A. In response to the question about permanent alopecia, that was their response. **And that's actually what's on their label.**

MR. MOORE: Move to strike.[12]

***

Q. Okay. And that's a sentence that you are ignoring in favor of the statement that you like better to the European regulator; correct?

MR. MICELI: Object to the form.

A. . . . Sanofi is the sponsor of this study. Sanofi set the definitions. Sanofi is sending information to regulatory agencies and **Sanofi is responsible for their label, which currently still reads 29 and 16**.

MR. MOORE: Move to strike.[13]

***

Q. And if those patients were not followed for their adverse event of alopecia for more than six months, the truth is, it is impossible to say that they have permanent chemotherapy-induced alopecia as defined in your report; isn't that true?

MR. MICELI: Object to the form.

---

[12] Feigal Dep. 311:18–312:13 (Jan. 27, 2023) (emphasis added).

[13] *Id.* at 314:7–21 (emphasis added).

> A. No. I'm going with how Sanofi analyzed their data. They continued to follow these patients. I don't know if other data exists in the medical records. They have a factory of people who do this study. **And they're responsible for truthful labeling. Unless you're telling me what they have on the label is false and misleading, I believe what they have.**
>
> BY MR. MOORE:
>
> Q. And what they have is ongoing at the last follow-up visit; correct?
>
> MR. MICELI: Objection to form.
>
> A. **Actually, I think to this date it's called permanent.**
>
> MR. MOORE: Move to strike. Move to strike the prior answer. Let's go off the record.[14]

Dr. Madigan

Dr. Madigan's Causation Opinions: In its ruling related to Dr. Madigan, this Court specifically stated, "Dr. Madigan will be precluded from testifying that Taxotere causes permanent alopecia."[15] Notwithstanding this Court's unequivocal ruling, Dr. Madigan freely testified on direct examination "that docetaxel causes permanent/irreversible alopecia."

> Q. . . . were you able to come to a conclusion as to whether or not, from a statistical correlation or statistical inference standpoint, whether Taxotere, or docetaxel, was statistically related to permanent chemotherapy-induced alopecia?
>
> MR. STRONGMAN: Objection; form.
>
> MR. MERRELL: Joined.
>
> A. So I conclude -- I concluded – I concluded that there is adequate statistical evidence **that docetaxel causes**

[14] *Id.* at 325:23–326:20 (emphasis added).

[15] Rec. Doc. 12098 at 4–6 (Order Granting in Part and Denying in Part Defs.' Mot. to Exclude Expert Test. of Dr. David Madigan).

permanent/irreversible alopecia.[16]

This was not an isolated mistake. Despite being admonished by the Court that Dr. Madigan "must take care to state only that the evidence shows an **association** between the two" and may not state causation,[17] Plaintiffs' counsel evoked a new phrase—"inference of causation"—in a direct effort to circumvent the Court's ruling:

> Q. . . . Do the findings of your metaanalysis [of TAX 316/301] support your conclusion of a statistical association and **inference of causation** between tax-- between docetaxel and permanent chemotherapy-induced alopecia?
>
> MR. STRONGMAN: Objection; form.
>
> A. Yes.[18]
>
> ***
>
> Q. Okay. Did the findings of your FAERS analysis support your conclusion of the statistical association and **inference of causation** between docetaxel and permanent chemotherapy-induced alopecia?
>
> MR. STRONGMAN: Objection; form.
>
> A. Yes, it's important.[19]
>
> ***
>
> Q. . . . Do your findings and review of the pharmacovigilance database and your analysis of it support your conclusion of a statistical association and **inference of causation** between docetaxel and PCIA?

---

[16] **Ex. F**, Madigan Dep. 43:23–44:12 (Nov. 14, 2022). The Court excluded this exact opinion from Dr. Madigan. *See* Rec. Doc. 12098 at 4 ("In his report for Plaintiff Kahn, Dr. Madigan concludes that 'there is adequate statistical evidence that docetaxel causes irreversible alopecia.' As revised, this opinion improperly encroaches on the second prong of the general causation inquiry—a prong that Dr. Madigan has not analyzed.").

[17] Rec. Doc. 12098 at 5 ("[Dr. Madigan] must take care to state only that the evidence shows an association between the two.").

[18] Ex. F, Madigan Dep. 73:9–19 (Nov. 14, 2022) (emphasis added).

[19] *Id.* at 112:12–19 (emphasis added).

A. Yes.[20]

***

Q. All right. Based upon all of the evidence that you have reviewed and that we've talked about today and the investigations and analyses you have performed, have you formed an opinion, to a reasonable degree of scientific certainty, that docetaxel use demonstrates a statistically significant increased risk and a **causal inference** for permanent chemotherapy-induced alopecia?

MR. STRONGMAN: Objection; form.

A. Yes, I have.[21]

Counsel's deliberate choice to have Dr. Madigan testify about causation and "an inference of causation" runs counter to the very limitations contemplated under CMO 36.

Dr. Madigan's "Chemo 2" Analysis: Plaintiffs' counsel also elicited testimony on an analysis Dr. Madigan purportedly conducted, but which appeared nowhere in the expert report provided to Sanofi. Dr. Madigan testified that he conducted a statistical analysis of TAX 316 where he removed the patients reporting ongoing alopecia from the TAC and FAC arms who switched to another chemotherapy regimen.[22] From this analysis, Dr. Madigan testified that he determined statistical significance between the TAC and FAC arms in TAX 316 alone:

Q. So if we take those nine people out, you end up with 20 and 7, is that respectively -- for TAC and FAC?

A. Yes.

Q. Okay. And have you assessed whether such a finding, 20 versus 7, is statistically significant?

A. Yes.

MR. STRONGMAN: Objection; form and undisclosed opinion.

---

[20] *Id.* at 124:20–125:2 (emphasis added).

[21] *Id.* at 141:11–21.

[22] **Ex. G**, Madigan Dep. 405:25–407:23 (Nov. 15, 2022).

> A. So yes. So I've done that analysis where you just remove the patients who had second – had chemo 2, and, indeed, then the difference between TAC and FAC is statistically significant.
>
> Q. In TAX 316 alone?
>
> A. In TAX 316 alone.[23]

Because Plaintiffs' counsel did not disclose this expert opinion in a supplemental report before the preservation deposition, Sanofi could not conduct a discovery deposition of Dr. Madigan under CMO 36.

Dr. Madigan's Regulatory Opinions: Dr. Madigan is not a regulatory expert, yet Plaintiffs' counsel elicited his opinions on drug manufacturers' regulatory obligations.[24] Dr. Madigan went so far as to suggest that the reason that there were more "reports" of irreversible alopecia in Sanofi's pharmacovigilance database than in the FAERS database as of 2008 was because "it's possible that they were never sent [by Sanofi]."[25]

> Q. Do drug companies have an obligation to monitor the drug safety -- their drug safety?
>
> A. Yes.
>
> MR. STRONGMAN: Just undisclosed opinion as well, outside the expertise as well.[26]
>
> ***
>
> Q. Okay. How were -- how could it be that Sanofi has events in its pharmacovigilance database that are not -- for irreversible alopecia that are not in the FAERS database?
>
> MR. STRONGMAN: Objection; form, undisclosed opinion.

---

[23] *Id.* at 407:1–23 (clarification from court reporter removed).

[24] *Id.* at 423:21–23.

[25] *Id.* at 409:6–411:16.

[26] *Id.* at 423:21–424:1.

> A. I don't know. I mean, it's possible that they were never sent. It's possible they were sent and never entered.[27]

Again, these opinions appear nowhere in Dr. Madigan's expert report, leaving Sanofi without CMO 36's safeguards before the preservation deposition.

LEGAL STANDARD

The Court's Order granting the PSC's Motion to Preserve Expert Testimony is interlocutory. Such orders "are not within the provisions of [Rule] 60(b), but are left within the plenary power of the court that rendered them to afford such relief from them as justice requires." *McKay v. Novartis Pharm. Corp.*, 751 F.3d 694, 701 (5th Cir. 2014) (quoting *Zimzores v. Veterans Admin.*, 778 F.2d 264, 266 (5th Cir. 1985)). This Court may revise its interlocutory orders "at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities." *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 2021 WL 1295090, at *1 (E.D. La. Apr. 7, 2021) (citing Fed. R. Civ. P. 54(b)). "Under Rule 54(b), 'the trial court is free to reconsider and reverse its decision for any reason it deems sufficient, even in the absence of new evidence or an intervening change in or clarification of the substantive law.'" *Austin v. Kroger Tex., L.P.*, 864 F.3d 326, 336 (5th Cir. 2017) (quoting *Lavespere v. Niagara Mach. & Tool Works, Inc.*, 910 F.2d 167, 185 (5th Cir. 1990), *abrogated on other grounds by Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 n.14 (5th Cir. 1994)). This power is "committed to the discretion of the district court, and that discretion is not cabined by the heightened standards for reconsideration governing final orders." *Id.* at 337 (quoting *Saint Annes Dev. Co. v. Trabich*, 443 F. App'x 829, 832 (4th Cir. 2011) (internal quotations omitted)).

[27] *Id.* at 411:8–16.

ARGUMENT

The Court may vacate CMO 36 for any reason it deems sufficient, and at least three exist here. First, the PSC's repeated violations of CMO 36 during the first two preservation depositions alone warrant vacating CMO 36. Second, by introducing new or previously excluded testimony during preservation depositions, the PSC has eliminated any perceived efficiencies gained under CMO 36. Finally, Sanofi will be prejudiced in the transferor courts, which may reasonably assume that testimony provided under CMO 36's protections is admissible. In addition, Sanofi requests that the Court strike the undisclosed and inadmissible testimony provided by Dr. Feigal and Dr. Madigan during their preservation depositions.

I. The Court Should Vacate CMO 36.

First, the PSC has repeatedly violated CMO 36 in the first two preservation depositions, warranting its withdrawal. Expert preservation depositions were premised on the explicit representations of the PSC and CMO 36's corresponding limitations that would safeguard Sanofi's rights in the transferor courts. But the PSC has disregarded these safeguards, including this Court's Rule 702 and evidentiary rulings. From Dr. Madigan, the PSC has elicited causation opinions that have been excluded *verbatim* by the Court. Nor did the Court's evidentiary rulings under Rule 407 stop Dr. Feigal from testifying on these excluded topics again and again.

Even more troubling is the PSC's calculated decision to ambush Sanofi with new opinions from its experts on the cusp of remand. Dr. Madigan did not disclose his "Chemo 2" analysis in his expert report. Yet the PSC intentionally elicited this testimony from Dr. Madigan during its examination. The same is true for Dr. Madigan's new regulatory opinions, including his rank speculation that Sanofi failed to provide FDA with adverse event reports. Dr. Feigal, in turn, provided undisclosed—and previously disclaimed—opinions on direct examination suggesting

that other non-Taxotere chemotherapies, including Adriamycin and Cytoxan, do not cause PCIA. Taken together, this is not an isolated expert problem. It is a PSC problem. And the Court should vacate CMO 36 as a result.

Second, vacating CMO 36 is the proper remedy because the PSC has proven that the process will complicate—not simplify—general expert testimony in the remand courts. MDL proceedings are designed to "prevent inconsistent pretrial rulings" and "conserve the resources of the parties, their counsel, and the judiciary." *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 220 F. Supp. 3d 1360, 1361 (J.P.M.L. 2016). This Court and the parties have committed significant time and resources to identify the scope of admissible evidence and expert testimony—rulings that are subject to significant deference on remand. *In re Ford Motor Co.*, 591 F.3d 406, 411 (5th Cir. 2009) ("In reviewing transferee court decisions under the law of the case doctrine, transferor courts should rarely reverse, because any widespread overturning of transferee court decisions would frustrate the principle aims of the MDL process and lessen the system's effectiveness."). But the PSC has proceeded in defiance of those rulings, which were explicitly incorporated into CMO 36. By doing so, the PSC has created the very problem it argued this process would avoid—re-litigating general expert testimony in the transferor courts.[28]

Third, because CMO 36 testimony is "subject to the Court's prior rulings as they relate to these witnesses," including "the Rule 702 rulings entered by this Court,"[29] a transferor court could reasonably assume that the preservation deposition testimony is consistent with this Court's disclosure obligations, Rule 702 orders, and evidentiary rulings. Plainly it is not. Instead, the

[28] Ex. A, Hr' Tr. 8:11–18 (Mar. 8, 2022) ("[Mr. Miceli:] This Court has overseen four different sets of briefing, four hearings on *Daubert* motions challenging the same experts and we've heard the same arguments time and time again. We don't need to hear them or we don't need to see them compounded by 200 this first round and another 200 the next round. This should be decided once and once only. And it conserves resources for the parties, for counsel, and the judiciary.").

[29] Rec. Doc. 14925 at 2, 6.

process to date seems little more than a calculated attempt to re-do, rather than preserve, expert testimony in the hopes that inadmissible testimony slips through to the transferor courts. If permitted to proceed, Sanofi faces substantial prejudice in the transferor courts because these experts' improper testimony will carry the perceived imprimatur of admissibility under CMO 36.

The prejudice to Sanofi will only increase if the Court does not vacate CMO 36. The PSC would like to preserve Dr. Laura Plunkett's testimony next. But the Court has never reviewed Dr. Plunkett's new reports, which are rife with inadmissible corporate state of mind and "bad company" opinions. Although the Court will consider Sanofi's Rule 702 challenge to Dr. Plunkett's new reports, the preservation depositions of Dr. Madigan and Dr. Feigal suggest that Dr. Plunkett, whose testimony was nearly stricken in full during the *Kahn* bellwether trial, may similarly choose to opine on excluded topics, multiplying the prejudice to Sanofi under CMO 36.

II. The Court Should Also Strike Dr. Feigal and Dr. Madigan's Undisclosed and Inadmissible Testimony.

In addition to vacating CMO 36, the Court should strike the undisclosed and inadmissible testimony provided by Dr. Feigal and Dr. Madigan that violated CMO 36. Specifically, the Court should strike Dr. Feigal's undisclosed causation opinions on other chemotherapies and her opinions that violate the Court's previous evidentiary rulings under Rule 407.[30] Likewise, the Court should strike Dr. Madigan's excluded causation and "inference of causation" testimony, as well as his undisclosed "Chemo 2" analysis and regulatory testimony.[31] This testimony violates CMO 36, and this Court should not leave it to the various transferor courts to enforce the limitations imposed by this Order.

[30] *See supra*, pp. 4–6.

[31] *See id.* at 6–10.

CONCLUSION

After Dr. Feigal and Dr. Madigan's expert preservation depositions, it is clear that the efficiencies contemplated under CMO 36 are illusory and that this experiment is doomed. By eliciting undisclosed and excluded opinions during these preservation depositions, along with testimony related to evidence excluded under Rule 407, the PSC has eliminated any possibility that the preservation depositions are usable without significant future litigation in the transferor courts. Essentially, there is no benefit to this process and the lawyers prosecuting these cases should be responsible for producing their own experts when the cases are returned. As a result, Sanofi requests that the Court vacate CMO 36 and strike Dr. Feigal and Dr. Madigan's undisclosed and inadmissible testimony.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 9, 2023, I electronically filed the foregoing with the Clerk of the Court using the ECF system, which sent notification of such filing to all counsel of record.

/s/ *Douglas J. Moore*

EXHIBIT A

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

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IN RE: TAXOTERE (DOCETAXEL)
PRODUCTS LIABILITY LITIGATION

Civil Action No. 16-MD-2740
Section "H"(5)
New Orleans, Louisiana
March 8, 2022

THIS DOCUMENT RELATES TO ALL CASES

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TRANSCRIPT OF MOTION TO PRESERVE EXPERT TESTIMONY
HEARD BEFORE THE HONORABLE JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE

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P R O C E E D I N G S

(Call to order of the court.)

THE CASE MANAGER: MDL No. 16-2740, *In Re: Taxotere Products Liability Litigation*.

MR. MICELI: Thank you.

Your Honor, I learned during our little break that they are going to be -- Mr. Strongman and Ms. Callsen are going to be arguing. I will try to address, if there's anything that I need to address, anything particular to a defendant, but I don't think my arguments do, but I may ask for a little indulgence on my rebuttal because I did not know I was going to be rebutting two arguments.

THE COURT: Okay.

MR. MICELI: But may it please the Court, Your Honor, we are here to discuss our motion, PSC's motion, to preserve general expert testimony. And when I began preparing for this argument, I went first to the transfer order that created this MDL and I looked at the purpose for centralization, and it's to eliminate duplicative discovery, prevent inconsistent trial rulings on common issues to all plaintiffs in the MDL, and to conserve the resources of the parties, their counsel, and the judiciary, not just this court, but all judiciary.

The PSC's proposal accomplishes all three of these goals. We eliminate duplicative -- preserving general

10:18:02AM 1 testimony will preserve and eliminate duplicative expert
10:18:07AM 2 discovery by allowing this court to address once again and
10:18:09AM 3 once and for all the issues of the 702 challenges to our
10:18:12AM 4 general experts, no case-specific experts, only those that
10:18:17AM 5 offer general testimony on, can Docetaxel cause permanent
10:18:27AM 6 chemotherapy-induced alopecia. It is a discrete scientific
10:18:30AM 7 question. It's not plaintiff-specific. It's not time
10:18:33AM 8 sensitive and the experts that testify on general cause and
10:18:35AM 9 the topics that impact upon general cause do not offer
10:18:40AM 10 case-specific opinions.
10:18:41AM 11 I know that we're going to hear about Dr. Bosserman.
10:18:45AM 12 Dr. Bosserman is the one that has sort of a dual role. She
10:18:50AM 13 talks about generally educating a jury on breast cancer, its
10:18:54AM 14 diagnosis, all of the options, and then she did that
10:18:58AM 15 predictive modeling based upon an individual plaintiff's
10:19:03AM 16 characteristics, the objective information from their
10:19:06AM 17 records. We are only talking about her general opinions. We
10:19:10AM 18 would not attempt to preserve and we could not attempt to
10:19:13AM 19 preserve that predictive modeling. That's an issue that will
10:19:17AM 20 be handled if the litigants decide to do so, if the plaintiff
10:19:22AM 21 litigant decides to do so, in the transferor court, that's an
10:19:26AM 22 issue that can be addressed on remand by the transferor court
10:19:30AM 23 judge.
10:19:30AM 24 And, subsequently, the PSC's general expert reports
10:19:34AM 25 have not --

have stated in their objection, they would have all 200 of those judges or judges that handle those 200 cases retread the same ground over and over and over again. And it's important to remember that this question is exactly the same; does Taxotere, Docetaxel -- can it cause PCIA? It's the same for every case. This is a perfect ripe issue to be decided in this court. And the efficiencies that can be gained, it's hard to challenge those.

We want to look for the most expeditious and efficient way to remand cases for trials in transferor courts. This Court has overseen four different sets of briefing, four hearings on *Daubert* motions challenging the same experts and we've heard the same arguments time and time again. We don't need to hear them or we don't need to see them compounded by 200 this first round and another 200 the next round. This should be decided once and once only. And it conserves resources for the parties, for counsel, and the judiciary.

The defendants never addressed these three-stated reasons for consolidation. Our brief is the only -- our memorandum is the only one that addresses the fact that this is an identical issue in every case and the most efficient way to handle it is here and here only.

Importantly, the manual on complex litigation predicts this. It endorses the use of videotaped deposition.

EXHIBIT B

Filed Under Seal

EXHIBIT B

Filed Under Seal

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

****

IN RE: TAXOTERE
(DOCETAXEL) PRODUCTS
LIABILITY LITIGATION

MDL NO. 2740
SECTION "H"

THIS DOCUMENT RELATES TO:
ALL CASES

****

The videotaped CMO 36 trial preservation deposition of ELLEN FEIGAL, PH.D., VOLUME I, taken in connection with the captioned cause, pursuant to the following stipulations before DIXIE VAUGHAN, Certified Court Reporter, January 26, 2023, beginning at 9:44 a.m.

Q. Okay. What are the popular -- what are the popular combination medicines that are used with Taxotere?

A. Well, the effective combination regimens that are used for this indication include Adriamycin, cyclophosphamide, methotrexate, 5FU, and then there are a variety of clinical trials that add other agents that can be used. I think the ones I looked at include Bevacizumab and Gemcitabine.

Q. With regard to Adriamycin, have you investigated whether or not reliable scientific evidence establishes that Adriamycin causes permanent chemotherapy-induced alopecia?

A. No, I do not have evidence to support that. May I also make a comment? I neglected to add Trastuzumab to the list of drugs that I've looked at.

Q. Thank you. I want to get back with Adriamycin. You say that you don't -- I want to make sure I'm repeating what you said. No, you do not have evidence to support that Adriamycin causes permanent chemotherapy-induced alopecia? Is that what you said?

MR. MOORE: Objection to form.

A. Yes, I do not have evidence to support causation.

BY MR. MICELI:

Q. And Adriamycin is the one that's been around since when?

A. I think we said 1974. I'd have to check the textbook on that, but I believe that's the correct date.

Q. And so from 1974 to 2004, did you find any evidence that Adriamycin can cause permanent chemotherapy-induced alopecia?

MR. MOORE: Object to form.

A. No. As I said, all I saw were anecdotal cases. Nothing -- nothing to support causation.

BY MR. MICELI:

Q. I'm going to ask you the same question about cyclophosphamide. And cyclophosphamide has been around since, I think you said, '59?

A. Correct. But check my facts.

Q. Okay. Did you find any reliable scientific evidence that said from between 1959 to 2004, when Taxotere was approved for early-stage breast -- use of adjuvant care in early-stage breast cancer, that cyclophosphamide can cause permanent chemotherapy-induced alopecia?

MR. MOORE: Object to form.

A. No.

BY MR. MICELI:

Q. Let's go back to talk about what your investigation included. The first thing you said, I think, was randomized -- Sanofi's randomized controlled trial?

A. Correct.

Q. What else did you look at?

A. A worldwide search of the literature.

Q. And anything else?

A. And Sanofi's pharmacovigilant database.

Q. Did you review anything else?

A. Oh, I reviewed other things, not necessarily related to causation.

Q. What are those things?

A. Well, I looked at Dr. Madigan's report where he was looking at the FAERS database for signals.

Q. Are you familiar with the FAERS database?

A. I am.

Q. And are you familiar with investigating drug signals?

A. Correct, yes.

EXHIBIT C

Filed Under Seal

EXHIBIT C

Filed Under Seal

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

****

IN RE: TAXOTERE
(DOCETAXEL) PRODUCTS
LIABILITY LITIGATION

MDL NO. 2740
SECTION "H"

THIS DOCUMENT RELATES TO:
ALL CASES

****

The videotaped CMO 36 trial preservation deposition of ELLEN FEIGAL, PH.D., VOLUME II, taken in connection with the captioned cause, pursuant to the following stipulations before DIXIE VAUGHAN, Certified Court Reporter, January 27, 2023, beginning at 8:10 a.m.

A. Correct.
Q. And it's a lengthy expert report, yes?
A. It's an expert report.
Q. Okay. And you included all of your opinions and conclusions. There's a section on conclusions at the end; correct?
A. Yes.
Q. And nowhere in your expert report do you render those opinions, do you? Nowhere in your expert report do you say, "I conducted the analysis and I have determined that Adriamycin cannot cause pCIA"?
A. I do not have that exact sentence, that's correct.
Q. And I think you were asked the same sort of questions about cyclophosphamide and Taxol as well by Mr. Miceli; correct?
A. Correct.
Q. And you didn't have any opinions about whether or not those agents can cause or are capable of causing pCIA in your expert report, did you?
A. In the expert report, I don't have that exact sentence, that's correct.
Q. In fact, you've been deposed numerous

A. I don't see the two-point -- I'm so sorry. I did not see the 2.96.

Q. Sorry.

A. There it is. It wasn't on the screen. Thank you.

Q. I'm sorry. And that's different than the number that's captured in Exhibit 24; correct?

A. Yes, it is.

Q. All right. And then look at this third patient in Exhibit 24. They were only followed for .32 years. Do you see that?

A. Yes, I do see that.

Q. And .32 years is an insufficient duration of follow-up to determine if that patient has permanent chemotherapy-induced alopecia.

A. If that's correct, that would be less than six months, that's correct.

Q. And so what I want to do is just ask you, given that we have these two tables, both coming from Sanofi, one definitely submitted to a regulator, one -- maybe it was or maybe there's a similar version submitted to a regulator -- that have different follow-up periods. How can we figure out which one's correct?

MR. MICELI: Objection to form.

A. Well, you're talking about apples and oranges. The follow-up that Sanofi did submit to the European agency in response to their question about persistent or long-lasting permanent alopecia came back with 29 and 16. That's Sanofi. I'm not manipulating the numbers. That is what they told the agency.

BY MR. MOORE:

Q. Yes.

A. In response to the question about permanent alopecia, that was their response. And that's actually what's on their label.

MR. MOORE: Move to strike.

BY MR. MOORE:

Q. So the statement you just made, the statement you just made is inconsistent with the highlighted statement at the bottom of the last paragraph submitted to the Canadian regulator; correct?

A. Now which document are you talking about?

Q. I'm going back to Exhibit No. 22.

A. So you're going back to the Canadian document?

Q. Yes.

ongoing does not necessarily mean that these adverse events were ongoing for the entire ten-year follow-up period; rather, it means that they were noted as ongoing at the last follow-up visit." Right?

A. You're reading that sentence correctly.

Q. Okay. And that's a sentence that you are ignoring in favor of the statement that you like better to the European regulator; correct?

MR. MICELI: Object to the form.

A. No. That wouldn't be an appropriate characterization of what I'm trying to communicate.

BY MR. MOORE:

Q. Okay.

A. Sanofi is the sponsor of this study. Sanofi set the definitions. Sanofi is sending information to regulatory agencies and Sanofi is responsible for their label, which currently still reads 29 and 16.

MR. MOORE: Move to strike.

BY MR. MOORE:

Q. Doctor, you would agree that the information communicated in these two submissions, can we at least agree it's inconsistent?

that they have permanent chemotherapy-induced alopecia is in those case report forms, isn't it?

A. I disagree.

MR. MICELI: Object to the form.

BY MR. MOORE:

Q. You disagree?

A. I don't know. Sanofi had obviously continued to follow them because they followed that patient for much longer. I don't know if there was some other way that they were assessing for it or not. But there's no pre -- I think what they're saying to you, what I'm interpreting, is that they don't have a precise timing of resolution and they're ongoing and permanent, and that's how they continued to characterize it to the agency.

Q. Does the truth matter, Dr. Feigal?

MR. MICELI: Object to the form.

A. The truth really matters. The truth really matters. And that's what I'm trying to give to the jury is the truth.

BY MR. MOORE:

Q. And if those patients were not followed for their adverse event of alopecia for more than six months, the truth is, it is impossible to say

that they have permanent chemotherapy-induced alopecia as defined in your report; isn't that true?

MR. MICELI: Object to the form.

A. No. I'm going with how Sanofi analyzed their data. They continued to follow these patients. I don't know if other data exists in the medical records. They have a factory of people who do this study. And they're responsible for truthful labeling. Unless you're telling me what they have on the label is false and misleading, I believe what they have.

BY MR. MOORE:

Q. And what they have is ongoing at the last follow-up visit; correct?

MR. MICELI: Objection to form.

A. Actually, I think to this date it's called permanent.

MR. MOORE: Move to strike. Move to strike the prior answer. Let's go off the record.

THE VIDEOGRAPHER: We're off the record, 9:44 a.m.

(Recess taken at 9:44 a.m. Back on record at 10:17 a.m.)

THE VIDEOGRAPHER: We're back on the record,

EXHIBIT D

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA
CASE NO. 2:16-cv-17039

ELIZABETH KAHN, Plaintiff, v. SANOFI S.A., SANOFI-AVENTIS U.S. L.L.C., SANOFI US SERVICE, INC., and AVENTIS-PHARMA S.A., Defendants.	) VIDEOCONFERENCE VIDEOTAPED) DEPOSITION OF:) ELLEN G. FEIGAL, M.D.

TRANSCRIPT of the stenographic notes of the proceedings in the above-entitled matter, as taken by and before ELLEN J. GODINO, CCR, RPR, CRCR, held via Zoom videoconference from multiple locations, with the witness located at 11806 Barranca Road, Santa Rosa Valley, California, on Friday, April 10, 2020, commencing at 10:58 a.m.

can do statistical analysis on the strength of the association. You can do a statistical test on the meta-analysis of the two randomized controlled clinical trials; and it's supported by the case reports and the pharmacovigilance information that came into the company.

So all three bodies of evidence; that's what I'm doing a general causation on. I didn't go through Bradford-Hill for all the other chemotherapy agents a breast cancer patient might take.

Q. I think it's implied in your last answer, but I just want to make sure it's clear for the record. In reaching your conclusions about whether Taxotere is capable of causing PCIA, did you determine whether Adriamycin is also capable of causing PCIA?

A. I did not do a Bradford-Hill analysis on Adriamycin.

Q. In reaching your conclusion on whether Taxotere is capable of causing PCIA, did you determine whether cyclophosphamide is capable of causing PCIA?

A. I did not do a Bradford-Hill analysis on cyclophosphamide.

Q. In reaching your conclusions about

EXHIBIT E

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	MDL No. 2740 Civil Case No. 2:17-CV-10817
This Document Relates to: Wanda Stewart v. Sandoz Inc. Civil Case No. 2:17-cv-10817	
IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	MDL No. 2740
THIS DOCUMENT RELATES TO ALICE D. HUGHES V. ACCORD HEALTHCARE, INC.	Civil Case No. 2:17-CV-10817

VIDEOCONFERENCE VIDEOTAPED DEPOSITION OF

ELLEN FEIGAL, M.D.

Tuesday, September 1, 2020

Reported By:

SUSAN A. SULLIVAN, CSR #3522, RPR, CRR

Job No. 183203

THE WITNESS: There's a lot in that question and I lost you so please restate that question.

Q BY MR. INSOGNA: Would it be an appropriate takeaway from reading your expert report to say that Adriamycin, cyclophosphamide, aromatase inhibitors or paclitaxel do not cause pCIA?

MR. MICELI: Object to the form.

THE WITNESS: What you can say from my report is about the causation of docetaxel/ Taxotere. I'm not opining on other products that aren't the topic for the litigation.

Q BY MR. INSOGNA: Okay. So I think that answered my question. So --

A Okay.

Q -- you could not take away from reading your report that those other medications do not cause pCIA, correct?

A I'm silent on that.

MR. MICELI: Objection to the form.

THE WITNESS: Yeah. I mean, I'm talking about risk and causal association of docetaxel/ Taxotere so, you know, I can't comment any further than that.

EXHIBIT F

Filed Under Seal

EXHIBIT F

Filed Under Seal

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	MDL NO. 2740 SECTION: "H" JUDGE MILAZZO
THIS DOCUMENT RELATES TO: ALL CASES	MAG. JUDGE NORTH

* *

The videotaped CMO 36 trial preservation deposition of DAVID B. MADIGAN, PH.D., VOLUME I, taken in connection with the captioned cause, pursuant to the following stipulations before RITA A. DEROUEN, Certified Court Reporter, Registered Professional Reporter, on November 14, 2022, beginning at 9:57 a.m.

my report. I was asked to investigate -- I'll just give you the shorter version of this.

I was asked to look at the FAERS data, the FDA's adverse event reporting system data, to see if a signal existed for docetaxel and irreversible alopecia. I was asked to review Sanofi's internal global pharmacovigilance databases with respect to the same question.

I was asked to review observational studies in the literature pertaining to the same question. And I was asked to look at relevant randomized clinical trials, as well as two trials in particular, one called TAX 311, one called TAX 301, and also to do a metaanalysis of those two studies. And then I was asked to look at various questions about how -- what happened over time in those studies.

Q. Okay. I'm going to take them in a little bit of reverse order. So randomized controlled trials, you said observational studies, Sanofi's pharmacovigilance database, and a FAERS analysis?

A. Yes.

Q. Okay. I'm going to try to walk through these with you. But before I do that, were you able to come to a conclusion about whether or not,

from a statistical correlation or statistical inference standpoint, whether Taxotere, or docetaxel, was statistically related to permanent chemotherapy-induced alopecia?

MR. STRONGMAN:

Objection; form.

MR. MERRELL:

Joined.

A. So I conclude -- I concluded -- I concluded that there is adequate statistical evidence that docetaxel causes permanent/irreversible alopecia.

BY MR. MICELI:

Q. Okay. I want to go into a little bit more detail on each of -- on each of these, but I want to get some definitions first. You told us a little bit about observational studies, randomized controlled trials, and you just mentioned something a moment ago, a metaanalysis.

Can you explain to the jury what a metaanalysis is.

A. Sure. So oftentimes there are many studies of a particular question, and so what a metaanalysis -- a metaanalysis is a statistical technique. What a metaanalysis seeks to do is to

A. Broadly speaking, yeah, very similar studies.

Q. Did they -- was the follow-up done exactly the same in both?

A. I'm reluctant to say absolutely yes because there might be tiny differences, I don't know. But generally speaking, these two studies are very, very similar.

Q. Okay. Do the findings of your metaanalysis support a conclusion that a statistical -- strike that.

Do the findings of your metaanalysis support your conclusion of a statistical association and inference of causation between tax -- between docetaxel and permanent chemotherapy-induced alopecia?

MR. STRONGMAN:

Objection; form.

A. Yes.

BY MR. MICELI:

Q. Do you understand the question?

A. Sorry, I said yes.

Q. I'm sorry, you said yes. Okay, thanks.

I want to show you -- if we could go to Exhibit 6 of your -- of this deposition, the

columns as you used for docetaxel? Can you -- let me restate that.

In conducting your FAERS analysis, did you use the exact same search criteria or analytic criteria to conduct the search for each of these chemotherapy drugs?

A. Yeah, I would refer to it as the end point. So I used the exact same -- actually, the same computer program, the exact same code, run the exact same analysis for each of these drugs in turn.

Q. Okay. Did the findings of your FAERS analysis support your conclusion of the statistical association and inference of causation between docetaxel and permanent chemotherapy-induced alopecia?

MR. STRONGMAN:

Objection; form.

A. Yes, it's important.

BY MR. MICELI:

Q. Why is that?

A. So it's good practice in these -- in these -- when addressing these kind of questions to look at different strands of evidence. They vary in terms of their force, their scientific

A. I do.

Q. And did the methodology that you employed, is it at all similar to what Dr. Hangai did in completing this clinical overview?

MR. STRONGMAN:

Objection; form.

A. Yeah, at a sufficiently high level, it's similar. She looked at different strands of evidence.

BY MR. MICELI:

Q. Okay. And concerning the clinical trials -- strike that.

I'm going to talk -- you can put that aside for a moment, Dr. Madigan.

The -- did your review of Sanofi's pharmacovigilance database and the information contained in it inform your opinion on -- pardon me, I want to make sure I mention this correctly. I don't want to operate off of memory.

Do your findings and review of the pharmacovigilance database and your analysis of it support your conclusion of a statistical association and inference of causation between docetaxel and PCIA?

MR. STRONGMAN:

Objection; form.

A. Yes.

BY MR. MICELI:

Q. Now let's talk about the fourth and final strand of evidence that you mentioned earlier today, and that is the observational studies. Can you tell us first -- we talked earlier today about what an observational study is.

Can you tell us how you went about selecting observational studies to review for your analysis.

A. So I conducted a search, I did this in September 2019, of electronic databases of the scientific literature, so PubMed, Embase, and SCOPUS. And I searched -- I searched those databases for relevant studies so I can -- the search terms are in my report.

And then I reviewed the hits, you know, what came back from that search, and I identified four -- four observational studies that were -- were germane.

Q. For the benefit of the juries that may watch this video, the jury that may watch this video, can you tell us what your search terms were and how you went about conducting that.

Objection; form.

A. Yes.

BY MR. MICELI:

Q. We've gone over the four strands of evidence that you had mentioned earlier. Are there any other strands of evidence that you evaluated to assess the relationship between docetaxel and permanent chemotherapy-induced alopecia?

A. No, I don't think so.

Q. All right. Based upon all of the evidence that you have reviewed and that we've talked about today and the investigations and analyses you have performed, have you formed an opinion, to a reasonable degree of scientific certainty, that docetaxel use demonstrates a statistically significant increased risk and a causal inference for permanent chemotherapy-induced alopecia?

MR. STRONGMAN:

Objection; form.

A. Yes, I have.

BY MR. MICELI:

Q. Okay. I'm going to have some additional questions. I would normally pass the witness right now.

EXHIBIT G

Filed Under Seal

EXHIBIT G

Filed Under Seal

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	MDL NO. 2740 SECTION: "H" JUDGE MILAZZO
THIS DOCUMENT RELATES TO: ALL CASES	MAG. JUDGE NORTH

* *

The videotaped CMO 36 trial preservation deposition of DAVID B. MADIGAN, PH.D., VOLUME II, taken in connection with the captioned cause, pursuant to the following stipulations before RITA A. DEROUEN, Certified Court Reporter, Registered Professional Reporter, on November 15, 2022, beginning at 8:38 a.m.

the documents about a patient in the TAX 316 study that has been switched from Taxotere, or docetaxel, to paclitaxel, and I believe -- I think we've already gone through it. It's back to Exhibit 21 that he showed you --

A. Correct.

Q. -- where a patient was switched from Taxotere, docetaxel, to paclitaxel and questioned you that -- concerning whether or not that patient should have been included in the number 29 demonstrated on Table 7 of the clinical study report.

Do you recall those questions?

A. I recall those questions in general, yes.

Q. And is today the first time you've ever been questioned about that?

A. Not about this general issue. I'm not sure if I ever saw this document before, Exhibit 21. But the general issue I've certainly been questioned about before.

Q. Have you -- when have you been questioned about that?

A. Oh, I don't know exactly, but in prior depositions.

Q. Okay. And based upon those prior -- that

prior series of questioning on that topic, did you go back and try to figure out how many patients in the TAC arm and how many patients in the FAC arm were switched from docetaxel to another chemotherapy drug?

A. Yes.

Q. And what did -- what was that called in your analysis when they were switched to a second chemotherapy regimen?

MR. STRONGMAN:

Object to the form.

A. I called it chemo 2.

BY MR. MICELI:

Q. Okay. And how many people received chemo 2 in the TAC arm?

A. That I don't have at my fingertips. I could find -- I could recover that, do the analysis again.

Q. Let me ask you this: How many people in the 29 received chemo 2?

A. Of the 29, nine of those patients were -- had chemo 2, what we're calling chemo 2.

Q. And how many patients in the 16 on the FAC arm received chemo 2?

A. Also nine.

Q. So if we take those nine people out, you end up with 20 and 7, is that respectively -- for TAC and FAC?

A. Yes.

Q. Okay. And have you assessed whether such a finding, 20 versus 7, is statistically significant?

A. Yes.

MR. STRONGMAN:

Objection; form and undisclosed opinion.

THE COURT REPORTER:

I'm sorry, objection; form, what?

MR. STRONGMAN:

Undisclosed opinion.

Go ahead.

A. So yes. So I've done that analysis where you just remove the patients who had second -- had chemo 2, and, indeed, then the difference between TAC and FAC is statistically significant.

BY MR. MICELI:

Q. In TAX 316 alone?

A. In TAX 316 alone.

Q. Okay. Just out of curiosity, because you were questioned about whether or not you published

A. No, it shouldn't.

BY MR. MICELI:

Q. In your report, you have a Table 6, do you not? Page 19.

A. Yep.

Q. Okay. When you performed your analysis on the Sanofi pharmacovigilance database, were you able -- were you able to identify manufacturer control numbers?

A. Yeah, I believe they're in there.

Q. Okay. Did you ever investigate whether those manufacturer control numbers can be found in the FAERS database?

MR. STRONGMAN:

Objection; form.

A. At some point I did, yes.

BY MR. MICELI:

Q. And what did you learn?

MR. STRONGMAN:

Objection; form.

A. So for -- for the reports in there that are included in -- the ones I looked at prior to, I think it was 2008, I do not recall why I stopped in 2008, but prior to 2008, none of them were in FAERS.

BY MR. MICELI:

Q. Okay. So if we look on page 20 of your report, in 2008, there are 47 -- is this the number right here -- 2008, 47 incidents of -- reports of irreversible alopecia, excluding those that are recovered?

A. Correct, using that -- using the methodology that's described there.

Q. And how did you come up with that methodology again?

A. So these terms came from Dr. Tosti.

Q. Okay. And using those terms, you searched "permanent," "irreversible," "bald," "baldness," "chronic," "persistent," "hair never grew back," "still have no hair," "no hair regrowth," "hair not regrowing," "hair has not returned," "alopecia ongoing"; those are the terms?

A. They're the terms, and then I also added kind of linguistic variance of those terms, because sometimes there might be a stray word in the middle like, "hair never ever grew back," for example.

Q. Okay.

A. So I looked for variants like that.

Q. And so by -- in using those terms, in

2008, you found 47 events of irreversible alopecia?

A. Yes.

Q. Okay. Of those 47, is that what you searched in the FAERS database to see -- to compare manufacturer control numbers?

A. Yes.

Q. Okay. How were -- how could it be that Sanofi has events in its pharmacovigilance database that are not -- for irreversible alopecia that are not in the FAERS database?

MR. STRONGMAN:

Objection; form, undisclosed opinion.

A. I don't know. I mean, it's possible that they were never sent. It's possible they were sent and never entered.

BY MR. MICELI:

Q. Okay. Thank you.

So up to this point, we know that those 47 events are not depicted as positive events in your FAERS analysis, correct?

MR. STRONGMAN:

Objection; form.

A. Correct.

BY MR. MICELI:

Q. If you had submitted any of your opinions for peer review, do you think they would have stood up here yesterday and questioned whether you were trying to create support for your opinions?

MR. STRONGMAN:

Objection; form.

A. I don't know.

BY MR. MICELI:

Q. Or that you were on some sort of a vendetta against Sanofi?

MR. STRONGMAN:

Objection; form.

A. I don't know.

BY MR. MICELI:

Q. Another colloquialism, Dr. Madigan, you're damned if you do and you're damned if you don't, aren't you?

MR. STRONGMAN:

Same objection.

BY MR. MICELI:

Q. Do drug companies have an obligation to monitor the drug safety -- their drug safety?

A. Yes.

MR. STRONGMAN:

Just undisclosed opinion as well,

outside the expertise as well.

THE COURT REPORTER:

Outside the what?

MR. STRONGMAN:

Expertise and his report.

MR. MICELI:

Nothing further. Thank you, Doctor.

THE COURT REPORTER:

Do we want to go off the record?

THE VIDEOGRAPHER:

This concludes the deposition. We're off the record, 12:12 p.m.

(Deposition adjourned at 12:12 p.m.)

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

In Re: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION

MDL NO. 2740

SECTION "H" (5)

THIS DOCUMENT RELATES TO: ALL CASES

NOTICE OF SUBMISSION

PLEASE TAKE NOTICE that Defendants sanofi-aventis U.S., LLC and Sanofi US Services, Inc. ("Sanofi") will bring for hearing the accompanying Motion to Reconsider and Vacate CMO 36 and to Strike General Experts' Improper Testimony on the 29th day of March, 2023, at 9:30 a.m., before the Honorable Jane Triche Milazzo of the United States District Court for the Eastern District of Louisiana, 500 Poydras Street, New Orleans, LA 70130.

Respectfully submitted,

/s/ *Douglas J. Moore*

Douglas J. Moore (Bar No. 27706)
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Counsel for sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc.

CERTIFICATE OF SERVICE

I hereby certify that on March 9, 2023, I electronically filed the foregoing with the Clerk of the Court using the ECF system which sent notification of such filing to all counsel of record.

/s/ Douglas J. Moore